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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,103	11/12/2003	Douglas Craig Scott	9118M2	5133

27752 7590 11/18/2005

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,103	SCOTT ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/26/04;4/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 27, 2004, and July 26, 2004 has been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "safe and effective" in claims 1,12, 13-14 and 16 is a relative term which renders the claim indefinite. The term "safe" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "particulate retentive agent" relates to an extremely large number of possible products and has no distinct meaning in the art. Examiner suggest that the limitations in claims 6 should replace the term "particulate retentive agent".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-35 of copending Application No. 10/706,104. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims are drawn to an chewable oral care dentifrice composition, having a retention index of 1 to about 4. The only difference between the instant application and the co-pending application is with respect to the retentive agent in claim 7 of the co-pending application where the retentive agent is hydroxyl-propylmethylcellulose, which is not claimed in the instant application. Thus the claims of the instant application are within the scope of the co-pending application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 5- 6-10 12-16 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Lawlor US 6,706,256 B2.

Lawlor discloses current claims1, 4 and 6 hydrogenated starch (retentive agent) calcium carbonate (current claims 1,13-14 and 16) from 10-50 % at col. 21 lines 48-40, wherein the composition is non-cariogenic at col. 20 line 43, a chewable solid unit at col. 15 line 46+ where it is referred to as hard and low boiled candy, wherein the composition is less than 65% at col. 15 lines 9-10, wherein the retentive agent is hydroxymethyl cellulose at col. 21 line 51 as in current claims 7 and 8, anticalculus agent at col. 10 line 31(current claim 9), fluoride ions current claims 9 at col. 11 line 48, the fluoride level is about 200-300 ppm (current claim 9) at col. 11 line 60 +,where the solid unit is a compressed tablet at col. 26 line 62 (current claim 14), water soluble buffers as sodium bicarbonate at col. 21 line 62. Lawlor also discloses the solubility as in current claims 2, 15 and 17 as 1g/100g at 25°C at col. 17 line 8 wherein the pH is from 3-10 at col. 22 line 5 + as in current claim 13. Claim 1 recites the solubility is less than 1g/30 g. As stated in the MPEP 2112.01"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658

(Fed. Cir. 1990), it is also anticipated that the tablet will take at least two minutes in the oral cavity absent factual evidence.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor, US 6,706,256, and Blue, US 4,978,521 in view of Aberg et al., WO 88/10110.

Lawlor discloses current claims1, 4 and 6 hydrogenated starch (retentive agent) 10% at col. 20 line 66, wherein the composition is non-cariogenic at col. 20 line 43, a chewable solid unit at col. 15 line 46+ where it is referred to as hard and low boiled candy, wherein the composition is less than 65% at col. 15 lines 9-10, wherein the retentive agent is hydroxymethyl cellulose at col. 21 line 51 as in current claims 7 and 8, anticalculus agent at col. 10 line 31(current claim 9), fluoride ions current claims 10 and 12 at col. 11 line 48, the fluoride level is about 200-300 ppm (current claim 13) at col. 11 line 60 +,where the solid unit is a compressed tablet at col. 26 line 62 (current claim 14), wherein the oral carrier is a flavor (current claim 15 at col. 23 line 20+, water soluble buffers as sodium bicarbonate at col. 21 line 62. Lawlor also discloses the solubility as in current claim 2 1g/100g at 25°C at col. 17 line 8.

Blue teaches an oral care dentrifice composition comprising: as in current claim 1 as having 30-65% retentive agent-calcium carbonate at col. 1 lines 54-55, wherein the retentive agent is calcium carbonate as in current claims 6 and 7, wherein the rententive agent is from 30-60% taught in the reference as 30-65% which is within applicants' claimed range (current claim 5) at col. 1 line 54-55, an effective amount of surfactant referred by reference as detergent at col. 1 lines 61-62 (current claim 1) a buffer as in current claim 1 and 11 at col. 1 line 56 as sodium bicarbonate, wherein the solid dosage form is a compressed tablet (current claim 10) at col. 3 lines 17-18, fluoride ion as in current claim 8 at col. 2 line 53 (see table), wherein the chewable composition has a

retention index of from 1-about 4, as stated in the MPEP, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)

With regards to current claims 2 and 4, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."

Therefore, the reference teaches the solubility of the retentive agent –calcium carbonate to be less than about 1g/30g at 25°C, as in current claims 1 and 2. Blue also teaches fluoride ion as 1000 parts per million (col. 1 line 51) which is far greater than the claimed invention, however this can be manipulated by one of ordinary skill in the art to obtain the claimed invention.

Blue, however, did not teach a non-effervescent solid dosage form per se.

Aberg et al., WO 88/10110 teach a non effervescent paste (page 5)

Preferably we provide a filling and polishing composition which comprises greater than about 50% by weight of the tablet and a carbon dioxide producing composition comprising less than about 25% by weight of the tablet to prevent excess foaming which would excessively thin the paste. The

Although the reference did not directly teach non-effervescent from the above, one of ordinary skill in the art would have known to implement the teachings for a non-

effervescent effect in a tablet because the tablet is chewable and not dissolved in water prior to use and it would be obvious for deposit of the active agent on the tooth surface.

Therefore one of ordinary skill in the art would have known to combine the teachings of the above cited reference to make and used the claimed invention at the time it was made because the invention is known to the ordinary skill in the art.

One of ordinary skill in the art would have combined the teachings of Lawlor and Blue with that of Aberg to make an oral dentrifice tablet that is non-effervescent, chewable, leave a substantial amount of the composition on the tooth surface because the active agent for a composition of a tooth tablet are well known within the art. One of ordinary skill in the art would know how to prepare a composition of this nature as the techniques are well known to the one of ordinary skill in the art.

One of ordinary skill in the art would have been motivated to combine the teachings of the above cited prior art and expect a successful result in doing so because the aim of preventive dentistry has been to improve the efficacy of oral hygiene in mammals.

With regards to the kit

Blue teaches an oral care dentrifice composition comprising: as in current claim 1 as having 30-65% retentive agent-calcium carbonate at col. 1 lines 54-55, wherein the retentive agent is calcium carbonate as in current claims 6 and 7, wherein the rententive agent is from 30-60% taught in the reference as 30-65% which is within applicants' claimed range (current claim 5) at col. 1 line 54-55, an effective amount of surfactant referred by reference as detergent at col. 1 lines 61-62 (current claim 1) a buffer as in

current claim 1 and 11 at col. 1 line 56 as sodium bicarbonate, wherein the solid dosage form is a compressed tablet (current claim 10) at col. 3 lines 17-18, fluoride ion as in current claim 8 at col. 2 line 53 (see table), wherein the chewable composition has a retention index of from 1-about 4 as stated in the MPEP.

Aberg et al., WO 88/10110 teach a non effervescent paste (page 5)

> **Preferably we provide a filling and polishing composition which comprises greater than about 50% by weight of the tablet and a carbon dioxide producing composition comprising less than about 25% by weight of the tablet to prevent excess foaming which would excessively thin the paste. The**

One of ordinary skill in the art would have combined the above prior art and made a kit that contains 30-65% retentive agent-calcium carbonate, a buffer, solid dosage form is a compressed tablet composition at the time the claimed invention was made in a kit, as kit is anything that contains the above mention composition/ formulation with information or instructions on how to use/administer.

Therefore one the skilled artisan would have been motivated to combine the above cited reference form a kit and expect a successful result in doing so.

Further, one of skill would have been motivated to combine the above teachings because the drugs used have been used before for the same function claimed by applicant.

Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blue, US 4,978,521, Aberg et al., WO 88/10110 as applied to claims 1-12 above, and further in view of Lawlor, US 6,706,256 B2 and Witt, US 6,350,438.

While the combined references above do not teach a method of use, Lawlor teaches a method (col. 6 line 15) current claim 13 wherein the pH range is from 3-10 as in current claim 13, at col. 22 lines 5+, calcium carbonate (current claims13-14 and 16) from 10-50 % at col. 21 lines 48-40, wherein the buffer is sodium bicarbonate at col. 21 line 61(current claims13-14 and 16), surfactants at col. 18 lines 42+ as in current claims13-14 and 16, chewable solid unit at col. 15 lines 46-47, non-cariogenic at col. 15 line 51as in current claims13-14 and 16, having flavor at col. 23 lines 12+, wherein the retentive agent has a water solubility of from 1g/30g or 1g/100 in current claims 13-17 as stated in the MPEP "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658
(Fed. Cir. 1990)
"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical
processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."

Witt et al teach a method for treating diseases of oral cavity (abstract), having a pH of 7-12 at col. 4 lines 59-60. Although Witt did not use the concentrations of calcium carbonate /retentive agent as claimed by applicant, the reference teaches incorporating the agents claimed to make an oral care.

Therefore one of ordinary skill in the art would have combined the teachings of the cited prior art supra with that of Lawlor and Witt, make a compressed chewable tablet that when dissolved in the mouth gives a basic pH ranging from 7-12 because the prior art teaches the limitations of the claimed invention. It is obvious for the composition of oral care to stay within the oral cavity for 2 minutes, if the oral care is in the form of a lozenges or a slow dissolving tablet.

One of ordinary skill in the art would have been motivated to combine the teachings and expect a successful result in doing so as the agents of the claimed invention are well known to the one of ordinary skill in the art and would have implemented all and be successful in the treatment of the oral cavity.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
10/20/05

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER